

K080088

JUN 11 2008



### 510(k) Summary

**Preparation Date:** January 11, 2008

**Applicant/Sponsor:** Biomet Sports Medicine, Inc.(formerly known as Arthrotek, Inc.)

**Contact Person:** Robert R. Friddle

**Proprietary Name:** Biomet Sports Medicine™ Anchor devices and ZipLoop™ Constructs

**Common Name:** Soft tissue anchor

**Classification Name:** Fastener, fixation, nondegradable, soft tissue (21 CFR 888.3040); Screw, fixation, bone (21 CFR 888.3040); Suture, nonabsorbable, synthetic, polyester (21CFR878.5000); Suture, nonabsorbable, synthetic, polyethylene (21CFR878.5000); Clip, implantable (21 CFR 878.4300); Marker, radiographic, implantable (21 CFR 878.4300); Staple, fixation, bone (21 CFR 888.3030); Fastener, fixation, biodegradable, soft tissue (21 CFR888.3030),

#### Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Multitak Suture System™ - K973015 (Bonutti Research, Inc.),  
Cruciate Ligament Button - K813581 (Biomet, Inc.),  
BioRaptor 2.9mm Suture Anchors - K053344 (Smith & Nephew, Inc.),  
Ti-Screw - K012503 (Biomet, Inc.),  
Hitch™ L-15 - K061657 (Biomet, Inc.),  
ALLthread™ Titanium - K042460 (Biomet, Inc.),  
ALLthread™ PEEK K060693 and K071569(Biomet, Inc.),  
Hitch™ PEEK - K060693(Biomet, Inc.),  
ALLthread™ Lactosorb® - K061389 (Biomet, Inc.)  
LactoScrew® L-15 - K012872, K033355 and K061801 (Biomet, Inc.)  
MicroMax™ - K040475 (Biomet, Inc.),  
Hitch™ L-15 - K061657(Biomet, Inc.),

**Device Description:** The Biomet Sports Medicine™ suture anchor devices (Ti-Screw, ALLthread™ Titanium, ALLthread™ PEEK, Hitch™ PEEK, ALLthread™ L-15, LactoScrew® L-15, MicroMax™ and Hitch™ L-15) Suture Anchors are internal fixation devices intended to aid in arthroscopic and orthopedic reconstructive procedures requiring soft tissue fixation due to injury or degenerative disease. The devices are available preloaded with suture and / or a ZipLoop™ Construct.

The Biomet Sports Medicine™ ZipLoop™ Constructs provide a flexible, adjustable means of soft tissue attachment in a manner that does not require the surgeon to tie a knot in sutures. The ZipLoop™ Constructs are available in three configurations and two strand materials.

**Intended Use:** Biomet Sports Medicine™ Anchors and ZipLoop™ Constructs are intended for use in soft tissue reattachment procedures in the shoulder, foot / ankle, elbow, knee, hand / wrist, and hip. The Biomet

Mailing Address:  
P.O. Box 587  
Warsaw, IN 46581-0587  
Toll Free: 800.348.9500  
Office: 574.267.6639  
Main Fax: 574.267.6137  
www.biomet.com

Shipping Address:  
56 East Ball Drive  
Warsaw, IN 46582

suture anchor devices have similar indications for use with one Indication for Use statement for non-resorbable anchor devices and another for resorbable anchor devices. ZipLoop™ Constructs may be packaged separately (one Indication for Use Statement covers a ZipLoop™ Construct packaged separately) or preloaded on suture anchors in place of sutures (an Indication for Use statement for non-resorbable anchor device with ZipLoop™ Construct and another for a resorbable anchor device with a ZipLoop™ Construct). Specific indications for use are as follows:

**Anchor devices without ZipLoop Constructs:**

Device Name: Ti-Screw, ALLthread™ Titanium, ALLthread™ PEEK, Hitch™ PEEK Anchors

**Ti-Screw, ALLthread™ Titanium, ALLthread™ PEEK and Hitch™ PEEK Anchors** are indicated for soft tissue reattachment procedures in the shoulder, foot/ankle, elbow, knee, hand/wrist, and hip. Specific indications are as follows:

**Shoulder:** Acromio-Clavicular Separation, Anterior Shoulder Instability Repair, Bankart Lesion Repairs, Biceps Tenodesis, Capsule Repair or Capsulolabral Reconstruction, Deltoid Repair, Rotator Cuff Repair, S.L.A.P Lesion Repairs

**Foot and Ankle:** Achilles Tendon Repair/Reconstruction, Hallux Valgus Reconstruction, Lateral/Medial Stabilization Repairs/Reconstruction, Midfoot/Forefoot Reconstruction/Repairs

**Elbow:** Biceps Tendon Reattachment, Biceps Tendon Reconstruction, Lateral/Medial Repairs, Lateral Epicondylitis Repair (Tennis Elbow Repair), Ulnar & Radial Collateral Ligament Reconstruction

**Knee:** ACL/PCL (**only for ALLthread™ Titanium and ALLthread™ PEEK anchors**), Iliotibial Band Tenodesis, Joint Capsule Closure, Lateral/Medial Collateral Ligament Repair, Patellar Ligament Repair, Patellar Tendon Repair, Patellar Realignment / Repair, Posterior Oblique Ligament Repair, VMO Advancement

**Hand and Wrist:** Collateral Ligament Repair (Gamekeeper's Thumb), Scapholunate Ligament Reconstruction, Tendon Transfers in Phalanx, Ulnar/Radial Collateral Ligament Reconstruction (**only for Ti-Screw, ALLthread™ Titanium and ALLthread™ PEEK**), Volar Plate Reconstruction

**Hip:** Labral

Device Name: ALLthread™ L-15, LactoScrew® L-15, MicroMax™ and Hitch™ L-15 Suture Anchors

**ALLthread™ L-15, LactoScrew® L-15, MicroMax™ and Hitch™ L-15 Suture Anchors** are indicated for soft tissue reattachment procedures in the shoulder, foot and ankle, elbow, knee, hand and wrist, and hip. Specific indications as follows:

**Shoulder:** Acromio-Clavicular Separation, Anterior Shoulder Instability Repair, Bankart Lesion Repairs, Biceps Tenodesis, Capsule Repair or Capsulolabral Reconstruction, Deltoid Repair, Rotator Cuff Repair, S.L.A.P Lesion Repairs

**Foot and Ankle:** Achilles Tendon Repair / Reconstruction, Hallux Valgus Reconstruction, Lateral/Medial Stabilization Repairs/Reconstruction, Midfoot / Forefoot Reconstruction / Repairs

**Elbow:** Biceps Tendon Reattachment, Biceps Tendon Reconstruction, Lateral / Medial Repairs, Lateral Epicondylitis Repair (Tennis Elbow Repair), Ulnar & Radial Collateral Ligament Reconstruction

**Knee:** ACL/PCL (**only for ALLthread™ L-15**), Iliotibial Band Tenodesis, Joint Capsule Closure, Lateral/Medial Collateral Ligament Repair, Patellar Ligament Repair, Patellar Tendon Repair, Patellar Realignment / Repair, Posterior Oblique Ligament Repair, VMO Advancement

**Hand and Wrist:** Collateral Ligament Repair (Gamekeeper's Thumb) (**not including Hitch™ L-15**), Scapholunate Ligament Reconstruction, Tendon Transfers In Phalanx (**not including Hitch™ L-15**), Ulnar/Radial Collateral Ligament Reconstruction (**only for ALLthread™ L-15 and LactoScrew® L-15**), Volar Plate Reconstruction (**not including Hitch™ L-15**)

**Hip:** Labral

#### **ZipLoop™ Constructs packaged separately:**

Device Name: Full, Bowtie and Half Zip-Loop™ Constructs

**Full, Bowtie and Half ZipLoop™ Constructs** are indicated for use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, knee, and hip.

When a ZipLoop™ Construct is packaged separately, the specific Indications for use are as follows:

**Shoulder:** Acromio-Clavicular Separation, Anterior Shoulder Instability Repair, Bankart Lesion Repairs, Biceps Tenodesis, Capsule Repair or Capsulolabral Reconstruction, Deltoid Repair, Rotator Cuff Repair, S.L.A.P Lesion Repairs

**Foot and Ankle:** Achilles Tendon Repair / Reconstruction, Hallux Valgus Reconstruction, Lateral/Medial Stabilization Repairs / Reconstruction, Midfoot/Forefoot Reconstruction / Repairs

**Elbow:** Biceps Tendon Reattachment, Biceps Tendon Reconstruction, Lateral / Medial Repairs, Lateral Epicondylitis Repair (Tennis Elbow Repair), Ulnar & Radial Collateral Ligament Reconstruction

**Knee:** ACL/PCL (**only for 2-0 or larger UHMWPE Full or Bowtie ZipLoop™ Construct**), Iliotibial Band Tenodesis, Joint Capsule Closure, Lateral/Medial Collateral Ligament Repair, Patellar Ligament Repair, Patellar Tendon Repair, Patellar Realignment / Repair, Posterior Oblique Ligament Repair, VMO Advancement

**Hand and Wrist:** Collateral Ligament Repair (Gamekeeper's Thumb), Scapholunate Ligament Reconstruction, Tendon Transfers In Phalanx, Ulnar/Radial Collateral Ligament Reconstruction (**only for 2-0 or larger UHMWPE Full and Bowtie ZipLoop™ Construct**), Volar Plate Reconstruction

**Hip:** Labral

When a ZipLoop™ Construct is packaged with a Biomet Sports Medicine™ Internal fixation device, please refer to the package insert included with the surgeon's choice of internal fixation device for specific indications.

#### **Anchor devices packaged with ZipLoop™ Constructs:**

Device Name: Ti-Screw, ALLthread™ Titanium, ALLthread™ PEEK and Hitch™ PEEK Anchors with ZipLoop Constructs

**Ti-Screw, ALLthread™ Titanium, ALLthread™ PEEK and Hitch™ PEEK Anchors with ZipLoop Constructs** are indicated for soft tissue reattachment procedures in the shoulder, foot/ankle, elbow, knee, hand/wrist, and hip. Specific indications are as follows:

**Shoulder:** Acromio-Clavicular Separation, Anterior Shoulder Instability Repair, Bankart Lesion Repairs, Biceps Tenodesis, Capsule Repair or Capsulolabral Reconstruction, Deltoid Repair, Rotator Cuff Repair, S.L.A.P Lesion Repairs

**Foot and Ankle:** Achilles Tendon Repair/Reconstruction, Hallux Valgus Reconstruction, Lateral/Medial Stabilization Repairs/Reconstruction, Midfoot/Forefoot Reconstruction/Repairs

**Elbow:** Biceps Tendon Reattachment, Biceps Tendon Reconstruction, Lateral/Medial Repairs, Lateral Epicondylitis Repair (Tennis Elbow Repair), Ulnar & Radial Collateral Ligament Reconstruction

**Knee:** ACL/PCL (**only for ALLthread™ Titanium and ALLthread™ PEEK anchors in conjunction with 2-0 or larger UHMWPE Full or Bowtie ZipLoop™ Construct**), Iliotibial Band Tenodesis, Joint Capsule Closure, Lateral/Medial Collateral Ligament Repair, Patellar Ligament Repair, Patellar Tendon Repair, Patellar Realignment / Repair, Posterior Oblique Ligament Repair, VMO Advancement

**Hand and Wrist:** Collateral Ligament Repair (Gamekeeper's Thumb), Scapholunate Ligament Reconstruction, Tendon Transfers in Phalanx, Ulnar/Radial Collateral Ligament Reconstruction (**only for TI-Screw, ALLthread™ Titanium and ALLthread™ PEEK in conjunction with 2-0 or larger UHMWPE Full or Bowtie ZipLoop™ Construct**); Volar Plate Reconstruction

**Hip:** Labral

Device Name: ALLthread™ L-15, LactoScrew® L-15, MicroMax™ and Hitch™ L-15 Suture Anchors with ZipLoop Constructs

**ALLthread™ L-15, LactoScrew® L-15, MicroMax™ and Hitch™ L-15 Suture Anchors with ZipLoop Constructs** are indicated for soft tissue reattachment procedures in the shoulder, foot and ankle, elbow, knee, hand and wrist, and hip. Specific indications as follows:

**Shoulder:** Acromio-Clavicular Separation, Anterior Shoulder Instability Repair, Bankart Lesion Repairs, Biceps Tenodesis, Capsule Repair or Capsulolabral Reconstruction, Deltoid Repair, Rotator Cuff Repair, S.L.A.P Lesion Repairs

**Foot and Ankle:** Achilles Tendon Repair / Reconstruction, Hallux Valgus Reconstruction, Lateral/Medial Stabilization Repairs/Reconstruction, Midfoot / Forefoot Reconstruction / Repairs

**Elbow:** Biceps Tendon Reattachment, Biceps Tendon Reconstruction, Lateral / Medial Repairs, Lateral Epicondylitis Repair (Tennis Elbow Repair), Ulnar & Radial Collateral Ligament Reconstruction

**Knee:** ACL/PCL (**only for ALLthread™ L-15 in conjunction with 2-0 or larger UHMWPE Full or Bowtie ZipLoop™ Construct**), Iliotibial Band Tenodesis, Joint Capsule Closure, Lateral/Medial Collateral Ligament Repair, Patellar Ligament Repair, Patellar Tendon Repair, Patellar Realignment / Repair, Posterior Oblique Ligament Repair, VMO Advancement

**Hand and Wrist:** Collateral Ligament Repair (Gamekeeper's Thumb) (**not including Hitch™ L-15**), Scapholunate Ligament Reconstruction, Tendon Transfers In Phalanx (**not including Hitch™ L-15**), Ulnar/Radial Collateral Ligament Reconstruction (**only for ALLthread™ L-15 and LactoScrew® L-15 in conjunction with 2-0 or larger UHMWPE Full or Bowtie ZipLoop™ Construct**), Volar Plate Reconstruction (**not including Hitch™ L-15**)

**Hip:** Labral

**Summary of Technologies:** The technological characteristics (material, design and sizing) of the current suture anchor devices are not changed and are similar or identical to the predicate devices. The technological characteristics of the new ZipLoop™ Constructs (material, design, sizing and indications) are similar or identical to the suture constructs provided pre-loaded with predicate devices.

**Non-Clinical Testing:** Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the devices were functional within their intended use.

**Clinical Testing:** None provided as a basis for substantial equivalence.

All trademarks are property of Biomet, Inc. unless otherwise specified.  
Multitak Suture System™ is a trademark of Bonutti Research Corporation.  
PEEK-OPTIMA® is a registered trademark of Invivo, Inc.  
BioRaptor™ is a trademark of Smith&Nephew.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Biomet Manufacturing Corp.  
% Mr. Robert R. Friddle  
Regulatory Specialist  
P.O. Box 587  
Warsaw, Indiana 46581-0587

JUN 11 2008

Re: K080088  
Trade/Device Name: Expanded indications for Biomet Sports Medicine™ Anchor  
Devices and ZipLoop™ Constructs  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HWC, MBI, JDR, MAI  
Dated: May 16, 2008  
Received: May 19, 2008

Dear Mr. Friddle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080088

Device Name: Ti-Screw, ALLthread™ Titanium, ALLthread™ PEEK, Hitch™ PEEK Anchors

Indications for Use:

**Ti-Screw, ALLthread™ Titanium, ALLthread™ PEEK and Hitch™ PEEK Anchors** are indicated for soft tissue reattachment procedures in the shoulder, foot/ankle, elbow, knee, hand/wrist, and hip. Specific indications are as follows:

**Shoulder:** Acromio-Clavicular Separation, Anterior Shoulder Instability Repair, Bankart Lesion Repairs, Biceps Tenodesis, Capsule Repair or Capsulolabral Reconstruction, Deltoid Repair, Rotator Cuff Repair, S.L.A.P Lesion Repairs

**Foot and Ankle:** Achilles Tendon Repair/Reconstruction, Hallux Valgus Reconstruction, Lateral/Medial Stabilization Repairs/Reconstruction, Midfoot/Forefoot Reconstruction/Repairs

**Elbow:** Biceps Tendon Reattachment, Biceps Tendon Reconstruction, Lateral/Medial Repairs, Lateral Epicondylitis Repair (Tennis Elbow Repair), Ulnar & Radial Collateral Ligament Reconstruction

**Knee:** ACL/PCL (**only for ALLthread™ Titanium and ALLthread™ PEEK anchors**), Iliotibial Band Tenodesis, Joint Capsule Closure, Lateral/Medial Collateral Ligament Repair, Patellar Ligament Repair, Patellar Tendon Repair, Patellar Realignment / Repair, Posterior Oblique Ligament Repair, VMO Advancement

**Hand and Wrist:** Collateral Ligament Repair (Gamekeeper's Thumb), Scapholunate Ligament Reconstruction, Tendon Transfers in Phalanx, Ulnar/Radial Collateral Ligament Reconstruction (**only for Ti-Screw, ALLthread™ Titanium and ALLthread™ PEEK**), Volar Plate Reconstruction

**Hip:** Labral

Prescription Use YES  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Michael J. Frank  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) <sup>42</sup> Number K080088

**Indications for Use**

510(k) Number (if known): K080088

Device Name: ALLthread™ L-15, LactoScrew® L-15, MicroMax™ and Hitch™ L-15 Suture Anchors

**Indications for Use:**

**ALLthread™ L-15, LactoScrew® L-15, MicroMax™ and Hitch™ L-15 Suture Anchors** are indicated for soft tissue reattachment procedures in the shoulder, foot and ankle, elbow, knee, hand and wrist, and hip. Specific indications as follows:

**Shoulder:** Acromio-Clavicular Separation, Anterior Shoulder Instability Repair, Bankart Lesion Repairs, Biceps Tenodesis, Capsule Repair or Capsulolabral Reconstruction, Deltoid Repair, Rotator Cuff Repair, S.L.A.P Lesion Repairs

**Foot and Ankle:** Achilles Tendon Repair / Reconstruction, Hallux Valgus Reconstruction, Lateral/Medial Stabilization Repairs/Reconstruction, Midfoot / Forefoot Reconstruction / Repairs

**Elbow:** Biceps Tendon Reattachment, Biceps Tendon Reconstruction, Lateral / Medial Repairs, Lateral Epicondylitis Repair (Tennis Elbow Repair), Ulnar & Radial Collateral Ligament Reconstruction

**Knee:** ACL/PCL (**only for ALLthread™ L-15**), Iliotibial Band Tenodesis, Joint Capsule Closure, Lateral/Medial Collateral Ligament Repair, Patellar Ligament Repair, Patellar Tendon Repair, Patellar Realignment / Repair, Posterior Oblique Ligament Repair, VMO Advancement

**Hand and Wrist:** Collateral Ligament Repair (Gamekeeper's Thumb) (**not including Hitch™ L-15**), Scapholunate Ligament Reconstruction, Tendon Transfers In Phalanx (**not including Hitch™ L-15**), Ulnar/Radial Collateral Ligament Reconstruction (**only for ALLthread™ L-15 and LactoScrew® L-15**), Volar Plate Reconstruction (**not including Hitch™ L-15**)

**Hip:** Labral

Prescription Use YES  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO  
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Neil R. Dyl  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number K080088

**Indications for Use**

510(k) Number (if known): K080088

Device Name: Full, Bowtie and Half Zip-Loop™ Constructs

Indications for Use:

**Full, Bowtie and Half ZipLoop™ Constructs** are indicated for use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, knee, and hip.

When a ZipLoop™ Construct is packaged separately, the specific indications for use are as follows:

**Shoulder:** Acromio-Clavicular Separation, Anterior Shoulder Instability Repair, Bankart Lesion Repairs, Biceps Tenodesis, Capsule Repair or Capsulolabral Reconstruction, Deltoid Repair, Rotator Cuff Repair, S.L.A.P Lesion Repairs

**Foot and Ankle:** Achilles Tendon Repair / Reconstruction, Hallux Valgus Reconstruction, Lateral/Medial Stabilization Repairs / Reconstruction, Midfoot/Forefoot Reconstruction / Repairs

**Elbow:** Biceps Tendon Reattachment, Biceps Tendon Reconstruction, Lateral / Medial Repairs, Lateral Epicondylitis Repair (Tennis Elbow Repair), Ulnar & Radial Collateral Ligament Reconstruction

**Knee:** ACL/PCL (**only for 2-0 or larger UHMWPE Full or Bowtie ZipLoop™ Construct**), Iliotibial Band Tenodesis, Joint Capsule Closure, Lateral/Medial Collateral Ligament Repair, Patellar Ligament Repair, Patellar Tendon Repair, Patellar Realignment / Repair, Posterior Oblique Ligament Repair, VMO Advancement

**Hand and Wrist:** Collateral Ligament Repair (Gamekeeper's Thumb), Scapholunate Ligament Reconstruction, Tendon Transfers in Phalanx, Ulnar/Radial Collateral Ligament Reconstruction (**only for 2-0 or larger UHMWPE Full and Bowtie ZipLoop™ Construct**), Volar Plate Reconstruction

**Hip:** Labral

When a ZipLoop™ Construct is packaged with a Biomet Sports Medicine™ Internal fixation device, please refer to the package insert included with the surgeon's choice of internal fixation device for specific indications.

Prescription Use YES  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO  
(21 CFR 807 Subpart C)

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Michael J. Smith  
(Division Sign-Off)

Page 3 of 4

Division of General, Restorative,  
and Neurological Devices

510(k)<sup>4-4</sup> Number K080088

Indications for Use

510(k) Number (if known): K080088

Device Name: Ti-Screw, ALLthread™ Titanium, ALLthread™ PEEK and Hitch™ PEEK Anchors with ZipLoop Constructs

Indications for Use:

**Ti-Screw, ALLthread™ Titanium, ALLthread™ PEEK and Hitch™ PEEK Anchors with ZipLoop Constructs** are indicated for soft tissue reattachment procedures in the shoulder, foot/ankle, elbow, knee, hand/wrist, and hip. Specific indications are as follows:

**Shoulder:** Acromio-Clavicular Separation, Anterior Shoulder Instability Repair, Bankart Lesion Repairs, Biceps Tenodesis, Capsule Repair or Capsulolabral Reconstruction, Deltoid Repair, Rotator Cuff Repair, S.L.A.P. Lesion Repairs

**Foot and Ankle:** Achilles Tendon Repair/Reconstruction, Hallux Valgus Reconstruction, Lateral/Medial Stabilization Repairs/Reconstruction, Midfoot/Forefoot Reconstruction/Repairs

**Elbow:** Biceps Tendon Reattachment, Biceps Tendon Reconstruction, Lateral/Medial Repairs, Lateral Epicondylitis Repair (Tennis Elbow Repair), Ulnar & Radial Collateral Ligament Reconstruction

**Knee:** ACL/PCL (only for ALLthread™ Titanium and ALLthread™ PEEK anchors in conjunction with 2-0 or larger UHMWPE Full or Bowtie ZipLoop™ Construct), Iliotibial Band Tenodesis, Joint Capsule Closure, Lateral/Medial Collateral Ligament Repair, Patellar Ligament Repair, Patellar Tendon Repair, Patellar Realignment / Repair, Posterior Oblique Ligament Repair, VMO Advancement

**Hand and Wrist:** Collateral Ligament Repair (Gamekeeper's Thumb), Scapholunate Ligament Reconstruction, Tendon Transfers in Phalanx, Ulnar/Radial Collateral Ligament Reconstruction (only for Ti-Screw, ALLthread™ Titanium and ALLthread™ PEEK in conjunction with 2-0 or larger UHMWPE Full or Bowtie ZipLoop™ Construct); Volar Plate Reconstruction

**Hip:** Labral

Prescription Use YES  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO  
(21 CFR 807 Subpart C)

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Niraj D. Shah for man  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

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Indications for Use

510(k) Number (if known): K080088

Device Name: ALLthread™ L-15, LactoScrew® L-15, MicroMax™ and Hitch™ L-15 Suture Anchors with ZipLoop Constructs

Indications for Use:

**ALLthread™ L-15, LactoScrew® L-15, MicroMax™ and Hitch™ L-15 Suture Anchors with ZipLoop Constructs** are indicated for soft tissue reattachment procedures in the shoulder, foot and ankle, elbow, knee, hand and wrist, and hip. Specific indications as follows:

**Shoulder:** Acromio-Clavicular Separation, Anterior Shoulder Instability Repair, Bankart Lesion Repairs, Biceps Tenodesis, Capsule Repair or Capsulolabral Reconstruction, Deltoid Repair, Rotator Cuff Repair, S.L.A.P Lesion Repairs

**Foot and Ankle:** Achilles Tendon Repair / Reconstruction, Hallux Valgus Reconstruction, Lateral/Medial Stabilization Repairs/Reconstruction, Midfoot / Forefoot Reconstruction / Repairs

**Elbow:** Biceps Tendon Reattachment, Biceps Tendon Reconstruction, Lateral / Medial Repairs, Lateral Epicondylitis Repair (Tennis Elbow Repair), Ulnar & Radial Collateral Ligament Reconstruction

**Knee:** ACL/PCL (only for ALLthread™ L-15 in conjunction with 2-0 or larger UHMWPE Full or Bowtie ZipLoop™ Construct), Illo-tibial Band Tenodesis, Joint Capsule Closure, Lateral/Medial Collateral Ligament Repair, Patellar Ligament Repair, Patellar Tendon Repair, Patellar Realignment/Repair, Posterior Oblique Ligament Repair, VMO Advancement

**Hand and Wrist:** Collateral Ligament Repair (Gamekeeper's Thumb) (not including Hitch™ L-15), Scapholunate Ligament Reconstruction, Tendon Transfers In Phalanx (not including Hitch™ L-15), Ulnar/Radial Collateral Ligament Reconstruction (only for ALLthread™ L-15 and LactoScrew® L-15 in conjunction with 2-0 or larger UHMWPE Full or Bowtie ZipLoop™ Construct), Volar Plate Reconstruction (not including Hitch™ L-15)

**Hip:** Labral

Prescription Use YES  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO  
(21 CFR 807 Subpart C)

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Michael J. Green  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

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